

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.*  
JEFFREY J. BIERMAN,

Plaintiff,

v.

Case No. 05-10557 (EFH)

ORTHOFIX INTERNATIONAL N.V.,  
ORTHOFIX, INC., ORTHOLOGIC  
CORP., DJO INCORPORATED,  
REABLE THERAPEUTICS, INC., THE  
BLACKSTONE GROUP, L.P., BIOMET  
INC., EBI, L.P., EBI HOLDINGS, INC.,  
EBI MEDICAL SYSTEMS, INC.,  
BIOELECTRON, INC., LBV  
ACQUISITION, INC., and, SMITH &  
NEPHEW, INC.,

Defendants.

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT BIOMET, INC.'S MOTION  
TO DISMISS THE AMENDED COMPLAINT OF JEFFREY J. BIERMAN**

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Pursuant to Fed. R. Civ. P. 8(a), 9(b) and 12(b)(6), and to the Court's July 6, 2010 Order, Defendant Biomet, Inc. ("Biomet") respectfully submits this individual Memorandum of Law in support of its Motion to Dismiss the Second Amended and Supplemental Complaint of Jeffrey J. Bierman.<sup>1</sup>

### **BACKGROUND**

In his sprawling Second Amended and Supplemental Complaint (the "SAC"), Relator Jeffrey J. Bierman ("Bierman") makes numerous allegations of misconduct amounting to alleged violations of both federal and local False Claims Acts ("FCA") against over a dozen defendants regarding the manufacture and billing of medical devices known as "Bone Growth Stimulators." Among these defendants are several – including Biomet – which, for nearly all of the allegations leveled against them, are "referred to collectively" as "EBI" (SAC ¶ 26).<sup>2</sup>

However, aside from generalized allegations that "defendants," or on occasion "EBI," committed various violations of these statutes (*see* SAC ¶¶ 113-123), not *one* allegation of misconduct is levied against Biomet specifically. Bierman alleges that Biomet, along with "its subsidiaries, design[s], manufacture[s] and market[s] products used primarily by musculoskeletal medical specialists in both surgical and non-surgical therapy," (*id.* ¶ 20) without alleging that Biomet itself had any role in the design, manufacture, or marketing of any of the Bone Growth

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<sup>1</sup> In addition to the arguments contained in this memorandum, Biomet has joined in, and expressly incorporates herein, the arguments in support of its Motion to Dismiss set forth in the Joint Memorandum in Support of Defendants' Motions to Dismiss the Second Amended and Supplemental Complaint of Jeffrey J. Bierman (the "Joint Memorandum"), filed on behalf of all of the defendants in this matter. Biomet also incorporates by reference the arguments presented in the Memorandum of Law in Support of the EBI Entities' Motion to Dismiss the Second Amended and Supplemental Complaint of Jeffrey J. Bierman (the "EBI Memorandum").

<sup>2</sup> These defendants are Biomet; EBI, LLC (f/k/a EBI, L.P.); EBI Holdings, LLC (f/k/a EBI Holdings, Inc.); EBI Medical Systems, LLC (f/k/a EBI Medical Systems, Inc.); and Bioelectron, Inc. (SAC ¶ 26.)

Stimulators that are the subject of Bierman's SAC.<sup>3</sup> Instead, Biomet is implicated in the alleged misconduct because (a) a business card allegedly provided to the Relator by an "EBI general manager for bone growth" in February 2007 was "headed 'Biomet'" (SAC ¶ 96) and (b) various "standard" forms and documents allegedly provided to the Relator by an "EBI executive" were emblazoned somewhere with the name "Biomet" or "Biomet Osteobiologics" (*Id.* ¶¶ 98, 112.) These allegations are insufficient as a matter of law and fail to meet the pleading requirements of Fed. R. Civ. P. 8(a), much less the heightened requirements of Rule 9(b) that apply to claims under the FCA. For these reasons, and in addition to the reasons set forth in the Joint Memorandum and in the EBI Memorandum, Bierman's claims against Biomet should be dismissed.

### **LEGAL STANDARD**

In order to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[A] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 555). Also, "'naked assertions' devoid of 'further factual enhancement'" are insufficient. *Id.* (quoting *Twombly*, 550 U.S. at 557). In essence, the plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.*

In addition, a Bierman must meet the heightened pleading standard of Rule 9(b) in alleging violations of the FCA. Thus, Bierman "must state with particularity the circumstances constituting fraud" for all claims asserted under both the federal FCA and any of its state or

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<sup>3</sup> By contrast, Relator alleges that EBI, LLC (f/k/a EBI, L.P.) – a "wholly owned subsidiary of Biomet" – "manufactures, markets, distributes, and directly bills for the SpinalPak and OrthoPak bone growth stimulators." (SAC ¶ 22.)

municipal counterparts. *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009). (See generally Joint Mem. 14-16.) To the extent the Bierman’s allegations are based on “information and belief,” “the complaint [must] set[ ] forth the facts on which the belief is founded.” *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir. 2004) (quoting *New Eng. Data Servs., Inc. v. Becher*, 829 F.2d 286, 288 (1st Cir. 1987)).

There are three purposes behind the Rule 9(b) particularity requirement: “(1) to place the defendants on notice and enable them to prepare meaningful responses; (2) to preclude the use of a groundless fraud claim as a pretext to discovering a wrong or as a ‘strike suit’; and (3) to safeguard defendants from frivolous charges which might damage their reputation.” *New Eng. Data Servs.*, 829 F.2d at 289. For these reasons, in a case involving multiple defendants (such as this one), “Rule 9(b) requires that fraud be alleged particularly as to each defendant.” *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 79 (D. Mass. 1998) (citing *Fleet Credit Corp. v. Sion*, 893 F.2d 441, 444-45 (1st Cir. 1990)); see also *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (“Rule 9(b) does not allow a complaint to merely lump multiple defendants together but ‘require[s] plaintiffs to differentiate their allegations when suing more than one defendant ... and inform each defendant separately of the allegations surrounding his alleged participation in the fraud.’” (quoting *Haskin v. R.J. Reynolds Tobacco Co.*, 995 F. Supp. 1437, 1439 (M.D. Fla.1998))).

Bierman’s allegations against Biomet fail to meet these pleading requirements.

## ARGUMENT

### BIERMAN FAILS TO ALLEGE A PLAUSIBLE CLAIM FOR RELIEF WITH PARTICULARITY AGAINST BIOMET.

Bierman's claims of FCA violations against Biomet fail because (1) he has not adequately alleged any direct violations by Biomet; and (2) he has failed to allege any basis for holding Biomet liable for the alleged conduct of its subsidiaries.

*First*, Bierman's Amended Complaint is completely bereft of any allegation of misconduct against Biomet. Instead, Bierman lumps Biomet together with certain other defendants under the moniker "EBI," and then proceeds to make broad allegations against these entities while making little effort distinguish between them. (*See, e.g.*, SAC ¶¶ 26, 31-32, 45, 81, 83, 89, 96-98, 112, 123.) Bierman, however, fails to allege that Biomet (as opposed to its subsidiaries) had any role in the design, manufacture, marketing or billing for any of the Bone Growth Stimulators that are the subject of his SAC. At most, Bierman alleges that the name "Biomet" appears on certain "standard" documents such as business cards, service agreements, and insurance information forms (SAC ¶¶ 96, 98, 112),<sup>4</sup> but this is unsurprising given that Biomet is EBI's corporate parent. The mere appearance of the name "Biomet" on these documents (or the fact that Biomet allegedly owns the copyright for these documents (*see* SAC ¶ 98)) does not amount to an allegation of wrongdoing. *See United States v. Ortho-McNeil Pharm., Inc.*, No. 03-C-8239, 2007 WL 2091185, at \*5 (N.D. Ill. July 20, 2007) (FCA allegations against corporate parent based on alleged conduct of subsidiary, without more, fail to satisfy *Twombly* pleading standard); *accord In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 391 (D. Mass. 2008) (reaching same conclusion because "[e]ach wrongful

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<sup>4</sup> Relator also alleges that a Certificate of Medical Necessity provided to him by an "EBI executive" was "headed 'Biomet Osteobiologics.'" (SAC ¶ 98.) Relator does not, however, allege that "Biomet Osteobiologics" is the same entity as Biomet, Inc.

act alleged by the relator implicates only Ortho-McNeil, not Johnson & Johnson, the corporate parent”). These allegations plainly fail to state a plausible claim for relief against Biomet for purposes of rule 8(a). Nor are they sufficient – even if they did overcome *Twombly* – to meet the heightened pleading requirements of Rule 9(b), because they simply do not put Biomet on notice of the particular allegations against it so as to “enable [it] to prepare [a] meaningful response....” *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, No. Civ. A. 01-10583-DPW, 2003 WL 21228801, at \*4 (D. Mass. May 21, 2003) (noting that the first purpose of the 9(b) particularity requirement is “to place the defendants on notice and enable them to prepare meaningful responses”), *aff’d*, 360 F.3d 220 (1st Cir. 2004).

*Second*, Bierman has failed to allege any basis for holding Biomet liable for the alleged conduct of its subsidiaries. “It is a general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation (so-called because of control through ownership of another corporation’s stock) is not liable for the acts of its subsidiaries.” *United States v. Bestfoods*, 524 U.S. 51, 61 (1998) (internal quotation marks and citation omitted); *see also United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 39 (D. Mass. 2000) (In the FCA context, “[o]wnership – even total ownership – of a corporation does not by itself impart the corporation’s liabilities to the owner, and that rule is not abated simply because the owner happens to be another corporation.”). In FCA cases, the “corporate veil” may be “pierced only if the parent and subsidiary lacked independence, the principals conducted their affairs with a requisite degree of ‘fraudulent intent,’ and failure to pierce the veil would work substantial injustice.” *Kneepkins*, 115 F. Supp. 2d at 39-40 (citing *United Elec., Radio & Mach. Workers v. 163 Pleasant St. Corp.*, 960 F.2d 1080, 1093 (1st Cir. 1992)).

Bierman has failed to plead any of these bases for piercing the corporate veil that stands between Biomet and EBI, LLC. In *Kneepkins*, the court dismissed claims against the corporate parent because “[t]he only fact alleged is [the parent’s] sole ownership of [the subsidiary],” which the court concluded was “plainly not enough.” *Kneepkins*, 115 F. Supp. 2d at 40. Here, as in *Kneepkins*, there is no allegation that Biomet has “filed a false claim itself,” or has “stripped [its subsidiaries] of assets.” *Id.* Thus, no basis for piercing the veil as to Biomet exists. See *Ortho-Mcneil*, 2007 WL 2091185, at \*5 (“West implies that Johnson & Johnson might be liable under a ‘piercing the corporate veil’ theory; however, he has pleaded no facts to support such a theory.”); *In re Pharm. Industry Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 391 (D. Mass. 2008) (same).

### **CONCLUSION**

For all of these reasons, as well as the reasons set forth in the Joint Memorandum, Bierman’s claims against Biomet should be dismissed.

Dated: August 17, 2010

Respectfully Submitted,

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